Notice of Agency Rulemaking Proposal

AGENCY: Department of Health and Human Services; Maine Center for Disease Control and Prevention

CHAPTER NUMBER AND TITLE: 10-144 CMR, Ch. 283; Rules and Regulations Relating to Testing Newborn Infants for Detection of Causes of Cognitive Disabilities and Selected Genetic Conditions

PROPOSED RULE NUMBER (leave blank; to be assigned by Secretary of State):

BRIEF SUMMARY: The proposed rule contains updates to Maine's newborn bloodspot screening (NBS) requirements, including (1) screening for additional conditions in conformity to recommendations by the U.S. DHHS; (2) protocols for collecting and storing NBS specimens; (3) reporting out-of-range-test results; and (4) releasing NBS samples for research purposes. The proposed rule includes additional terms and definitions, along with a revised construction of the rule format, for improved readability. Proposed changes are in conformity to the U.S. DHHS recommendations for newborn screening, supported by the U.S. Health Resources and Services Administration (HRSA) for infants and children under the Public Health Service Act.

Date, time and location of PUBLIC HEARING (if any): June 20, 2018; 9 a.m. Conference Room 16: Maine CDC/Key Plaza; 286 Water Street; Augusta, Maine 04333

COMMENT DEADLINE: June 30, 2018

CONTACT PERSON FOR THIS FILING (include name, mailing address, telephone, fax, TTY, e-mail): Bridget Bagley, 286 Water Street, 11 State House Station, Augusta, ME 04333-0011; Tele: (207)287-9394; bridget.bagley@maine.gov

CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (if different):

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (if any): None anticipated.

STATUTORY AUTHORITY FOR THIS RULE: 22 MRS §§ 1532 and 1533

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different):

AGENCY WEBSITE: http://www.maine.gov/dhhs/mecdc/rules/

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: Tera.Pare@maine.gov

☑ The summary provided above is for publication in both the newspaper and website notices.

☐ The summary provided above is for the newspaper notice only. Title 5 §8053, sub-§5 & sub-§7, ¶D. A more detailed summary is attached for inclusion in the rule-making notice posted on the Secretary of State's website. Title 5 §8053, $sub-\S 3$, ¶D & $sub-\S 6$.

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT Jose Clause DATE: 5/22/18

(authorized signature)

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
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^{*} Check one of the following two boxes.